K060378

6.0 510(k) Summary

MAR 9 2006

Submitter's Name / Contact Person

Timothy J. Kappers, MBA, RAC
Director, Quality Systems, Regulatory & Clinical Affairs
Vital Images, Inc.
5850 Opus Parkway, Suite 300
Minnetonka, MN 55343

General Information

Trade Name	Vitrea2®, Version 3.8.1 Medical Image Processing Software
Common / Usual Name	System, Image Processing, Radiological
Classification Name	LLZ, Class II, CFR 21 892.2050
Predicate Devices	• Vitrea2, Version 3.8 (K052632) Vital Images, Inc. • RTist™ (K033955) Siemens Molecular Imaging, LTD. • Fusion7D™ (K020546) Siemens Molecular Imaging, LTD. • CA-1500: AutoPoint™ (K040028) R2 Technologies, Inc. • Filling Defect Indicator: Pulomary Artery PE™ (K041380) R2 Technologies, Inc.

Device Description

The Vitrea2 system is a medical diagnostic device that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices.

The Vitrea2 system provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The Vitrea2 user interface follows typical clinical workflow patterns to process, review, and analyze digital images, including:

- Retrieve image data over the network via DICOM
- Display images that are automatically adapted to exam type via dedicated protocols
- Select images for closer examination from a gallery of up to six 2D or 3D views
- Interactively manipulate an image in real-time to visualize anatomy and pathology
- Annotate, tag, measure, and record selected views
- Output selected views to standard film or paper printers, or post a report to an Intranet Web server or export views to another DICOM device
- Retrieve reports that are archived on a Web server

Intended Use

Vitrea2® is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. In addition, Vitrea2 Version 3.8.1 has the following additional indication:

Fusion7D™

The product registers pairs of anatomical and functional volumetric images (e.g. MRI-SPECT, MRIPET, CT-SPECT, CT-PET), or pairs of anatomical volumetric images (e.g. MRI-MRI, CT-CT and MRICT) as a means to ease the comparison of image volume data by the clinician. The result of the registration operation aims to help the clinician obtain a better understanding of the joint information that would otherwise have to be compared visually. This is useful for a wide range of clinical and therapeutic applications. It is important to note that the clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard procedures, including visual comparison of the separate unregistered images. The device is a complement to these standard procedures.

RTist™

RTist is a software application, intended to display and visualize 2D & 3D multimodality (i.e. CT, MRI, and PET) medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant medical image data within the system and/or across computer networks at distributed locations utilizing standard PC hardware.

The volume and linear measurement functions are intended for evaluation and quantification of tumor measurements, location/displacement study, analysis and evaluation of both hard and soft tissues. The software also supports interactive segmentation of the region of interest (ROI), automated contouring of multi-slice ROI and labeling of 'avoidance' structure(s) during critical evaluation.

Typical users of this system are trained professionals, including but not limited to radiologists, clinicians and technicians. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis.

ImageChecker™ CT Lung v2.0 System

The ImageChecker® CT Lung v2.0 System is a computer-aided detection (CAD) system designed to assist physicians in softcopy review of digital computed-tomography (CT) images of the chest. The ImageChecker CT Lung workstation displays composite views of 2D cross-sections and 3D volumes of chest CT images, including findings or regions of interest identified by the physician or computer-aided detection (CAD) findings.

The system assists physicians in the characterization, classification, and tracking of suspicious candidate thoracic abnormalities in terms of size, dimension, shape, density, and position, and thus aids in the patient management care decision process.

The system is intended to be used as an adjunct, alerting the physician – after an initial reading of the scan – to regions of interest that may have been overlooked.

AutoPoint™ Temporal Comparison Tool

The AutoPoint temporal comparison tool consists of software that enables physicians to view, analyze, register and compare new and previous series of thoracic CT images. The software package assists the physicians by calculating volume change and doubling time of selected segmented candidate thoracic abnormalities (such as pulmonary and pleural nodules and lesions) found on these images.

The software is designed to assist the radiologist in characterization and classification of these suspicious candidate thoracic abnormalities in terms of size, dimension, shape and position and thus aid in the patient management care decision process.

Pulmonary Artery PE™ (Patency Exam)

The Pulmonary Artery Patency Exam tool is used during the review of contrast-enhanced computed tomography (CT) images of the chest. This software tool enables the radiologist to view and analyze regions of the image containing low density within vascular structures that may be indicative of filling defects or other intravascular abnormalities.

The software is designed to assist the radiologist in characterization and classification of these suspicious candidate thoracic abnormalities in terms of density, size, dimension, shape and position, thus aiding in the patient management care decision process.

Predicate Device Comparison

The Vitrea2, Version 3.8.1 system and its predicate devices allow for the analysis, communication and media interchange of digital images acquired from a variety of acquisition devices. All devices support the DICOM protocol for communication of images with other medical imaging devices.

Summary of Studies

The software utilized was designed, developed, tested, and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating and maintenance.

The Vitrea2, Version 3.8.1 system will successfully complete integration testing/verification testing prior to Beta validation. Software Beta testing/validation will be successfully completed prior to release. In addition, potential hazards have been studied and controlled by a Risk Management Plan.

Conclusion

The Vitrea2, Version 3.8.1 system has similar intended uses as the predicate devices and has very similar technological characteristics. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, the Vitrea2, Version 3.8.1 system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2006

Vital Images, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K060378
Trade/Device Name: Vitrea2®, Version 3.8.1 Medical Image Processing Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 10, 2006
Received: February 14, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): _____
Device Name: Vitrea2®, Version 3.8.1 Medical Image Processing Software

Vitrea2 is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea2 Version 3.8.1 adds the following previously FDA-cleared software applications to the currently marketed Vitrea2 system: Fusion7D, RTist, ImageChecker CT Lung v2.0 System, AutoPoint Temporal Comparison Tool, and the Pulmonary Artery PE (Patency Exam).

Prescription Use ✓ _____ *Over-The-Counter Use* _____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060378